REMARKS

Claims 10 and 29-44 are pending in this divisional application. Applicants have elected, with traverse, to prosecute the Group 2 claims (claims 10, 30, 31, 33, 36, 37 and 39-42) drawn at least to antibodies against SEQ ID NO:1 or SEQ ID NO:3.

Restriction Requirement

Applicants reiterate their position that the Restriction Requirement is improper for all of the reasons enumerated in the Response to Restriction Requirement which was mailed on November 1, 2002. Applicants submit that the subject matter of Groups III-VII (i.e., claims 29, 32, 34, 35, 38, 43 and 44) should all be considered with Group II since there would be no burden on the Examiner to do so. That is, claims 29, 32, 34, 35, 38, 43 and 44 relate to methods of making or using the antibodies of Group II and, therefore, overlapping searches would be necessary for all of the claims.

Rejoinder

Applicants submit that, upon allowance of any product claim, the methods of claims 29, 32, 34, 35, 38, 43 and 44, which depend therefrom, should be rejoined and examined in accordance with the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in Light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products.

Claim rejections under 35 U.S.C. § 112, second paragraph

Claims 36 and 39 have been rejected under 35 U.S.C. § 112, second paragraph for alleged indefiniteness as depending from claims directed to non-elected inventions. Applicants submit that, once product claim 10 is allowed, the method claims 35 and 38 from which claims 36 and 39 depend will be rejoined. Since the patentability of method claims 35 and 38 relies on the novelty and patentability of claim 10, and these claims do not expand the scope of the products recited in claim 10, claims 35 and 38 will be allowable upon rejoinder. Once this has been accomplished, claims 36 and 39

will depend from allowable method claims 35 and 38. Accordingly since Applicants are confident that the Examiner will withdraw the 35 U.S.C. § 102(a) rejections against claim 10 and allow claim 10 after considering the arguments submitted below, this rejection of claims 36 and 39 will be moot.

Claim rejections under 35 U.S.C. § 102(a)

Claims 10, 30, 31, 33, 36, 37 and 39-42 have been rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Singleton et al. (26 August 1997; J. Cell. Sci. 110:2099-2107). The Office Action asserts that:

- Singleton et al. teach secretory carrier membrane protein (SCAMPs) SCAMP3 having 98.1% sequence identity to SEQ ID NO:1...Singleton et al. teach making antibodies to SCAMP3 using the sequence SPTEPKNYGSYSTQ, which is found within instant SEQ ID NO:1. Given that antibodies bind epitopic structures rather than sequences per se, and the identity between SCAPM3 [sic] and SEQ ID NO:1 is high, the antibody made by Singleton et al. will also bind polypeptides having SEQ ID NO:1 (Claim 10, 30, 36, 39). (Office Action at page 3.)

- Singleton et al. also teach SCAMP2 having 99% sequence identity to SEQ ID NO:3...Singleton et al. teach making antibodies to SCAMP2 using the sequence QPSVEPTOPTPO [sic], which is found within instant SEQ ID NO:3. Given that antibodies bind epitopic structures rather than sequences per se, and the identity between SCAPM2 [sic] and SEQ ID NO:3 is high, the antibody made by Singleton et al. will also bind polypeptides having SEQ ID NO:3 (Claim 10, 30, 36, 39). (Office Action at page 3.)

- The antibodies were in composition (Claim 31, 37, 40), and the antibodies were labeled via coupling to hemocyanin (Claim 33). Claims 41 and 42 are being considered to be anticipated as well because there appears to be no difference in the antibody made by a Fab expression library or and [sic] immunoglobulin expression library. (Office Action at page 3.)

Applicants strongly disagree with the Examiner's position and traverse the rejection.

The MPEP is clear with regard to the requirements for making a rejection under any subsection of 35 U.S.C. § 102:

> for anticipation under 35 U.S.C. 102, ***the reference must teach every aspect of the claimed invention either explicitly or impliedly***. Any feature not directly taught must be inherently present. (*MPEP 706.02* at page 700-21, Rev. 1, Feb. 2003) [Emphasis added.]

The polypeptide sequences taught by Singleton et al. do not ***teach every aspect of the claimed invention either explicitly or impliedly***. The Examiner has admitted that the polypeptide sequences taught by Singleton et al. are either 98.1% identical to SEQ ID NO:1 (SCAMP3) or 99% identical to SEQ ID NO:3 (SCAMP2). (Office Action at page 3.) It is, therefore, possible to make an antibody to either SEQ ID NO:1 or SEQ ID NO:3 that does not bind to either SCAMP3 or SCAMP2 respectively. Such an antibody is recited in claim 10 as "An isolated antibody ***which specifically binds*** to a polypeptide comprising the amino acid sequence of SEQ ID NO:1 or SEQ ID NO:3." By **"specifically binding"** to SEQ ID NO:1 or SEQ ID NO:3, the claimed antibody ***must*** bind to a polypeptide consisting of SEQ ID NO:1 or SEQ ID NO:3. Accordingly, so long as there are differences, even just one amino acid residue, between the amino acid sequences recited in claim 10 and those disclosed in Singleton et al., an antibody can be produced that can specifically bind to the polypeptides recited in claim 10 and not those of SCAMP3 and SCAMP2.

Evidence in support of this premise may be found in Abaza et al., J. Protein Chem. (1992) 11:433-444 (Attachment 1). As taught by Abaza et al., a single amino acid substitution outside the antigenic site on a protein effects antibody binding. This provides scientific support of Applicants' assertion that so long as there are differences, even just one amino acid residue, between the amino acid sequences of claim 10 and those of the prior art, an antibody can be produced that can specifically bind to the polypeptides recited in claim 10 and not those of the prior art. Accordingly, given the amino acid differences between SEQ ID NO:1 and SCAMP3, and SEQ ID NO:3 and SCAMP2, one of skill in the art could produce an antibody which binds to the polypeptides recited in claim 10 alone and without cross-reactivity to other polypeptides even those which have extensive sequence identity to SEQ ID NO:1 and SEQ ID NO:3.

Once claim 10 (and therefore claims 30, 36 and 39) has been correctly characterized and considered in its proper context, the ancillary issues regarding antibodies in composition (claims 31, 37 and 40), having a label (claim 33), or being produced by either a Fab expression library or an immunoglobulin expression library (claims 41 and 42) become moot. For at least the above reasons, Applicants respectfully request that this rejection be withdrawn.

Claim rejections under 35 U.S.C. § 102(b)

Claims 10, 30, 31, 33, 36, 37 and 39-42 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Brand et al. (1993; EMBO J. 12(10) 3753-3761). The Office Action asserts that:

- Brand et al. teach secretory carrier membrane protein (SCAMPs) SCAMP37 having 51% sequence identity to SEQ ID NO:1...Brand et al. teach making antibodies to SCAMP37, resulting in antibody SG7C12. Given that antibodies bind epitopic structures rather than sequences per se, and the identity between SCAMP37 and SEQ ID NO:1 is high, the antibody made by Brand et al. will also bind polypeptides having SEQ ID NO:1 (Claim 10, 30, 36, 39). (Office Action at page 4.)

- SCAMP 37 also has 57.4% sequence identity to SEQ ID NO:3. (Office Action at page 4.)

- The antibodies were in composition (Claim 31, 17, 40), and the antibodies were labeled via coupling to Affigel-Hz...(Claim 33). Claims 41 and 42 are being considered to be anticipated as well because there appears to be no difference in the antibody made by a Fab expression library or and [sic] immunoglobulin expression library. (Office Action at page 4.)

Applicants strongly disagree with the Examiner's position and traverse the rejection.

The MPEP is clear with regard to the requirements for making a rejection under any subsection of 35 U.S.C. § 102:

> for anticipation under 35 U.S.C. 102, ***the reference must teach every aspect of the claimed invention either explicitly or impliedly***. Any feature not directly taught must be inherently present. (*MPEP 706.02* at page 700-21, Rev. 1, Feb. 2003) [Emphasis added.]

The polypeptide sequence taught by Brand et al. does not ***teach every aspect of the claimed invention either explicitly or impliedly***. The Examiner has admitted that the polypeptide sequence taught by Brand et al. (SCAMP37) is either 51% identical to SEQ ID NO:1 or 57.4% identical to SEQ ID NO:3. (Office Action at page 4.) It is, therefore, possible to make an antibody to either SEQ ID NO:1 or SEQ ID NO:3 that does not bind to SCAMP37. Such an antibody is recited in claim 10 as "An isolated antibody ***which specifically binds*** to a polypeptide comprising the amino acid sequence of SEQ ID NO:1 or SEQ ID NO:3." By **"specifically binding"** to SEQ ID NO:1 or SEQ ID NO:3, the claimed antibody ***must*** bind to a polypeptide consisting of SEQ ID NO:1 or SEQ ID

NO:3. Accordingly, so long as there are differences, even just one amino acid residue, between the amino acid sequences recited in claim 10 and those disclosed in Brand et al., an antibody can be produced that can specifically bind to the polypeptides recited in claim 10 and not that of SCAMP37.

Evidence in support of this premise may be found in Abaza et al., J. Protein Chem. (1992) 11:433-444 (Attachment 1). As taught by Abaza et al., even a single amino acid substitution outside the antigenic site on a protein effects antibody binding. This provides scientific support of Applicants' assertion that so long as there are differences, even just one amino acid residue, between the amino acid sequences of claim 10 and those of the prior art, an antibody can be produced that can specifically bind to the polypeptides recited in claim 10 and not those of the prior art. Accordingly, given the amino acid differences between SEQ ID NO:1, SEQ ID NO:3 and SCAMP37, one of skill in the art could produce an antibody which binds to the polypeptides recited in claim 10 alone and without cross-reactivity to other polypeptides even those which have extensive sequence identity to SEQ ID NO:1 and SEQ ID NO:3 (which SCAMP37 does not).

Once claim 10 (and therefore claims 30, 36 and 39) has been correctly characterized and considered in its proper context, the ancillary issues regarding antibodies in composition (claims 31, 37 and 40), having a label (claim 33), or being produced by either a Fab expression library or an immunoglobulin expression library (claims 41 and 42) become moot. For at least the above reasons, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In light of the above remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at the number listed below.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

Respectfully submitted,

INCYTE CORPORATION

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Attachment:

Attachment 1: Abaza et al., J. Protein Chem. (1992) 11:433-444